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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,206

Applicant(s)

PARKER ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 55 and 56 is/are allowed.
- 6) ☒ Claim(s) 33-37, 39 and 41-54 is/are rejected.
- 7) ☒ Claim(s) 38 and 40 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 33-35, 37, 47-48, and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,755,226 to Carim et al. Carim et al. teaches a light transmitter 326 having a plurality of transmitting fibers, a light detector 330 having a plurality of light detector fibers, and means for utilizing a non-pulsatile element 500. (Fig. 4 and column 6, lines 43-47 of Carim et al.). In regard to claim 34, the pulsatile element is utilized. (Fig. 4 and column 6, lines 43-47 of Carim et al.). In regard to claim 35, Carim et al. shows an optical fiber bundle 326 that has thousands of fibers. (column 15, line 62 to column 16, line 6 of Carim et al.). In regard to claim 37, blood oxygen saturation is determined. (Abstract of Carim et al.). In regard to claims 47-48, Carim et al. shows an optical fiber bundle 330 that has thousands of fibers in Fig. 4, which means that the light detectors includes at least 12 detector fibers. In regard to claim 50, the

light is transmitted through the tissue. (Fig. 4 of Carim et al.). In regard to claim 51-52, light in the bandwidth of 650 to 1350 nm is used.

3. Claims 33-34, 37, 39, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,078,833 to Hueber. Hueber teaches a method and apparatus for determining hemoglobin concentration and glucose. (column 2, lines 1-4 of Hueber). Hueber et al. teaches a plurality of emitting and detecting fibers. (Fig. 2 of Hueber).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 33, 36, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,407,290 to Wilber in view of U.S. Patent 5,755,226 to Carim et al. Wilber teaches an apparatus and method for determining several chemical analytes including oxygen saturation, glucose, hematocrit, and carbon dioxide in blood. (column 11, line 62 to column 12, line 16 of Wilber). Wilber does not teach a plurality of transmitting fibers or a plurality of detection fibers. Wilber teaches that the light sources can be LEDs or other sources. (column 3, lines 46-61 of Wilber). Carim et al. teaches a

lamp 312 that is delivered using a plurality of optical fibers. (Fig. 4 of Carim et al.).

Such a light emitting system falls within the scope of using other light sources as suggested by Wilber. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the lamp and optical fibers of Carim et al. for the LEDs of Wilber since Wilber teaches that other sources can be used and Carim et al. teaches such a source. Wilber also teaches that an array of detectors can be used. Carim et al. teaches a series of detectors that are used with optical fibers. (Fig. 4 of Carim et al.). Such a light detecting system falls within the scope of providing an array of detectors as suggested by Wilber. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the array of detector and optical fibers of Carim et al. in the device of Wilber since Wilber teaches that a detector array can be used and Carim et al. teaches such a detector array. In regard to claim 43, a digital processor is disclosed for carrying out the signal processing, which inherently means that a computer program is used.

6. Claims 33 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,064,896 to Rosenthal in view of U.S. Patent 5,755,226 to Carim et al. Rosenthal teaches an apparatus and method for determining glucose and temperature. (column 5, line 66 to column 6, line 3 of Rosenthal). Rosenthal does not teach a plurality of transmitting fibers or a plurality of detection fibers. Rosenthal teaches the use of introducing means and detecting means of electromagnetic energy but Rosenthal does not teach the particular form that these elements take. (column 8,

lines 19-30 of Rosenthal). Carim et al. teaches a lamp 312 that is delivered using a plurality of optical fibers and a series of detectors that are used with optical fibers. (Fig. 4 of Carim et al.). . (Fig. 4 of Carim et al.). Such elements would fulfill the requirements of providing introducing and detecting means of electromagnetic energy as set forth in Rosenthal. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the light and detecting systems of Carim et al. in the method and apparatus of Rosenthal since Rosenthal teaches the use of introducing and detecting means and Carim et al. teaches such means. In regard to claim 43, a digital processor is disclosed for carrying out the signal processing, which inherently means that a computer program is used. In regard to claim 44, a multiple linear regression analysis is used. (column 7, lines 1-7 of Rosenthal).

7. Claims 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,078,833 to Hueber as applied to claim 33, and further in view of U.S. Patent 4,752,115 to Murray, Jr. et al. Hueber et al. teaches a plurality of emitting and detecting fibers. (Fig. 2 of Hueber). Hueber et al. does not teach a particular fiber. Murray, Jr. et al. teaches a 250-micron diameter fiber. Such a fiber would fulfill the requirements of providing fibers as set forth by Hueber. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the fibers of Murray, Jr. et al. in the device and method of Hueber since Hueber requires the use of fibers and Murray, Jr. et al. teaches such fibers.

8. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,407,290 to Wilber in view of U.S. Patent 5,755,226 to Carim et al. as applied to claim 42, and further in view of U.S. Patent 5,673,692 to Schulze et al. Wilber teaches an apparatus and method for determining several chemical analytes including oxygen saturation, glucose, hematocrit, carbon dioxide, and hemoglobin in blood. (Abstract and column 11, line 62 to column 12, line 16 of Wilber). Wilber does not teach the use of a temperature sensor. Schulze et al. teaches the use of a temperature sensor. (Abstract of Schulze et al.). Schulze et al. further teaches that the monitoring of temperature is important in patient care. (column 1, lines 12-17 of Schulze et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the temperature sensor of Schulze et al. in the combination since the monitoring of temperature is important to patient care.

9. Claims 51 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,078,833 to Hueber as applied to claim 33, and further in view of U.S. Patent 6,097,975 to Petrovsky et al. Hueber does not teach that the transmitting fiber transmits wavelengths of 500.9, 528.1, 549.5, 561.1, 572.7, 586.3, and 800-1100 nm. Hueber teaches the use of laser diodes. (column 8, lines 10-20 of Hueber). Petrovsky et al. teaches that a broad based light source can be a substitute for laser diodes. Petrovsky teaches this by showing alternative embodiments of a light source: one that is broad based source (a flash lamp) and one that used laser diodes. Therefore, it would

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have been obvious to one having ordinary skill in the art at the time the invention was substitute the broad based light source for the laser diodes since Petrovsky et al. teaches that they are suitable substitutes for each other. In regard to claims 53-54, since a broad based source is used, the entire spectrum of light is transmitted through the transmitting fibers.

Allowable Subject Matter

10. Claims 38 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 55-56 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest that:

$$SO_2 = \frac{100 * (OXI + 0.43)}{1.5}$$

or

$$OXI = \left(\frac{e-d}{11.7} - \frac{d-c}{11.6} \right) * \frac{100}{HbI}$$


or


$$HbI = \left(\frac{b-a}{27.1} + \frac{c-b}{21.4} + \frac{c-e}{23.3} + \frac{c-f}{13.6} \right) * 100$$

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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